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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,766	12/08/2003	Deb K. Chatterjee	0942.4200002	9843
26111	7590	08/31/2005	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			MONSHIPOURI, MARYAM	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/728,766	<b>Applicant(s)</b> CHATTERJEE ET AL.	
	<b>Examiner</b> Maryam Monshipouri	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                                   |                                                                                        |
|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>filed 10/28/04</u> | 6) <input type="checkbox"/> Other: ____                                                |

### DETAILED ACTION

Claim 1 is under examination on the merits. Claims 2-68 are canceled.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of making polypeptide in the form of inclusion bodies comprising obtaining a bacterial host cell comprising a first nucleic acid encoding said polypeptide operatively linked to a second nucleic acid encoding an inclusion partner protein and cultivating said bacterial cell under conditions favoring production of said polypeptides in inclusion bodies in said host cell, does not reasonably provide enablement for methods of making a polypeptide in the form of inclusion bodies utilizing any host cells comprising said first and second nucleic acids.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification fails to teach which host cells beyond those of bacterial origin may be used in the claimed method. No examples of such host cells are provided either. Current state of the art indicates that many host cells such as mammalian host

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cells are not necessarily capable of expressing claimed fusion products in inclusion bodies.

Therefore due to lack of sufficient information and examples provided in the specification and due to unpredictability of prior art as to which host cells are likely to express the claimed first and second nucleic acids in the form of inclusion bodies one of skill in the art has to go through the burden of undue experimentation in order to screen for those host cells that may be used in the claimed invention and as such the claim goes beyond the scope of the disclosure.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 as recited is directed to a method of use of a **genus** of host cells that have been inadequately described in the specification.

The specification fails to teach which host cells (from which origin) are capable of being utilized for expressing the claimed fusion products in inclusion bodies. The genus of host cells claimed is directed to all sorts of cells from all sources and origins most of which are unlikely to express the claimed nucleic acids of this invention in inclusion bodies. Therefore some additional information about the properties and characteristics of the host cells utilized is necessary that is currently lacking in the disclosure.

The specification merely discloses a **single species** of the claimed genus (namely bacterial host cells ) which is insufficient to put one of skill in the art in

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possession of the attributes and features of all species within the claimed genus.

Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Since said the host cells claimed are inadequately described a method of use of said host cells are inadequately described as well.

Applicant is reminded that that claim 1 is further subjected to written description rejection for recitation of the term "inclusion partner protein" defined in page 12 of the specification as any protein or fragment, portion or derivative thereof which forms inclusion bodies. The specification fails to provide sufficient structural information about the genus of inclusion partner proteins which may successfully be expressed as fusion products with the desired protein in the appropriate host cell as inclusion bodies. Said **genus**, as broadly claimed, is only supported by a **single species**, namely bacterial thioredoxin, which is insufficient to put the skilled artisan in possession of all members of the genus. Since said genus is inadequately described method of use of said genus, as claimed, is inadequately described as well.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by McCoy et al. (U.S. Patent No. 5,270,181, issued 12/1993). McCoy teaches a method of expression of (see Example 4) of a fusion product of human Bone Morphogenic Protein 2 (BMP-2) gene and thioredoxin (which is an inclusion partner protein, according to the specification) encoding gene in E.coli (strain GI724), wherein said fusion product is expressed almost exclusively as insoluble cellular fraction (in the form of inclusion bodies) at 37 °C on a media containing tryptophan, prior to this invention. Even though McCoy does not explicitly teach about its method favoring the formation of inclusion bodies the fact that its DNA expression product is totally expressed in insoluble form (as inclusion bodies) implies that its method favors formation of said bodies, anticipating claim 1 of this invention.

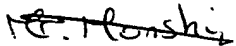
**No claims are allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Maryam Monshipouri Ph.D.

Primary Examiner

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